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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,665	12/11/2001	Shaileshkumar Ramanlal Desai	033218-018	4860

7590

06/20/2003

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EXAMINER
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QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/20/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/014,665

Applicant(s)

DESAI ET AL.

Examiner

Sabiha Naim Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-32 is/are pending in the application.
- 4a) Of the above claim(s) 22-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 22-32 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Acknowledgement is made of the response filed in paper no. 7. Amendments are entered. Claims 1-20 and 22-32 are pending. Finality of the rejection mailed in paper No. 8 is withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

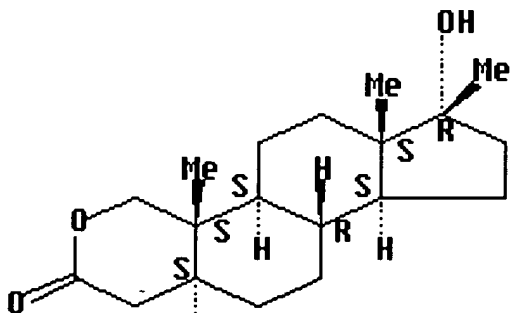
Rejection under 103 (a) is maintained for the following reasons; others are withdrawn because claims are amended. New action is as follows.

***Claim Rejections - 35 USC § 103***

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pappo et al. (US Patent 3,128,283). See the entire document especially examples. Presently claimed invention is drawn to method of making oxandrolone.

Registry # 26624-15-7

CN 2-Oxa-5.alpha.-androstan-3-one, 17.alpha.-hydroxy-17-methyl



Oxandrolone

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**1. Determining the scope and contents of the prior art.**

Prior art teaches synthesis of 17-Hydroxy, 17-methyl-2-oxa androstan-3-one, see examples 5,6, 8, 9 and 10. Pappo et al. teach preparation of structurally similar 2-oxa androstan-3-ones, which embraces applicant's claimed invention. Compound 17beta -Hydroxy, 17alpha -methyl-5alpha androstan-3-one mestanolone is oxidized by osmium tetra oxide with lead tetra acetate in acidic condition. Sodium borohydrate is used to reduce 1-oxo derivatives.

**2. Ascertaining the differences between the prior art and the claims at issue.**

Presently claimed invention differ from the reference in claiming a broader synthetic method for preparing oxandrolone by not defining any conditions and reagents for hydroxylation, reduction etc. See independent claims 1 and 6. In claim 20 only oxidation of mestanolone using IBX (o-iodo benzoic acid) in step (a) is described; reagent and conditions are not specific in other steps.

**3. Resolving the level of ordinary skill in the pertinent art.**

Since the prior teaches all the steps and reagents for the preparation of oxandrolone art one skilled in the art would be motivated to prepare additional

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oxandrolone by using the reagents and method available at the time of invention by using lead tetra acetate, Osmium tetroxide and other reagents as in the present claim steps a, b, c and d.

**4. Considering objective evidence present in the application indicating obviousness or nonobviousness.**

It would have been obvious to one skilled in the art to prepare oxandrolone by any method taught by the prior art as no specific method for preparation is claimed in these claims. Therefore, any method would be a prior art for claims 1-20.

Claim 20 differs from claim 6 in mestanolone oxidation by IBX. Since it has not been established any advantage or criticality of using IBX in first step, use of any oxidizing agent for oxidation of mestanolone would have been obvious at the time of invention.


Claims 1-5 and 15-17 and 19 were said to be allowable because of applicant's disclosure that this method gives good yield of oxandrolone as compared to prior art method. However, since no data has been provided, the said claims are now rejected on the same basis as all other claims for the reasons cited above.

No unexpected results are seen. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone

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number is 703-305-3910. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
BIHA QAZI, PH.D  
PRIMARY EXAMINER

June 17, 2003